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EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/062,197

Applicant(s)

CHEN ET AL.

Examiner

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
4a) Of the above claim(s) 8-16 and 20-28 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7, 17-19 and 29 is/are rejected.
7) ☒ Claim(s) 7 is/are objected to.
8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 26 October 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-7, 17-19, and 29.

DECLARATION UNDER 37 C.F.R. § 1.132

The declaration filed under 37 C.F.R. § 1.132 filed 26 October 2004 is approved and has overcome the previous rejection under 35 U.S.C. § 102(a) (refer to the 'Office Action' mailed 26 July 2004).

Claims Rejected Under 35 U.S.C. § 112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

NEW MATTER

Claims 1-7, 17-19, and 29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 and all claims dependent therefrom are rejected under 35 U.S.C. § 112 1st paragraph. Claim 1 has been amended to recite “scanning the specimen at a first magnification” and “acquiring and recording a second image...at a second, higher magnification” which is considered new matter. The original claim 1 recited “scanning the specimen at a low magnification” and “acquiring and recording a second image...at a high second magnification”, which implied ranges/values of magnification that were considered to be “low” and “high” and were considered unclear (refer to the 35 U.S.C. § 112 2nd Paragraph Rejections *VAGUE AND INDEFINITE* in the ‘Office Action’ mailed 26 July 2004). The original claims appeared to recite that an image is scanned at a low magnification (i.e. 2x-10x range) and then scanned at a high magnification (i.e. 20x-40x), however, such ranges of magnification were unclear. Instant claim 1 appears to indicate that an image is scanned at a first magnification (i.e. 2x) followed by the acquisition and recording of a second image at a higher magnification (2.1x), wherein the higher magnification is interpreted to be in the range of low magnification. There does not appear to be support throughout the specification for the concept that “a second, higher magnification” is higher than “a first magnification”, such that the second higher magnification is within a “low” magnification range as encompassed by the instant claims. Thus, claims 1-7, 17-19, and 29 are considered NEW MATTER.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 17-19, and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 1 and all claims dependent therefrom recite the limitation “a second, higher magnification” which is vague and indefinite. It is unclear if Applicants regard “a second, higher magnification” than “the first magnification” or some other unknown magnification. Clarification of the metes and bounds, via clearer claim language, is requested.

Claim 29 recites the limitation “a dye sensitive for cells” which is vague and indefinite. The term sensitive implies some form of sensitivity (i.e. criteria/ parameter) for which the dye has for cells. Therefore, it is unclear what Applicants’ regard as the criteria/parameters that establishes a dye to be “sensitive” for cells. Clarification of the metes and bounds, via clearer claim language, is requested.

LACK OF ANTECEDENT BASIS

Claim 5 recites the limitation “wherein the system” which lacks proper antecedent basis. Absent from instant claim 1 (which claim 5 depends from) is any indication/recitation of “the system”. Therefore, the above limitations lack proper antecedent basis. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. § 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. § 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

Claims 1, 4, and 17-19 are rejected under 35 U.S.C. § 102(e) as being anticipated by Douglass et al. (U.S. Patent Number 6,215,892 B1).

Douglass et al. discloses a method for automated cell analysis of biological specimens that are scanned at a first (i.e. 10x) and higher (i.e. 40x or 60x) magnification to acquire images that are analyzed to determine candidate cell objects of interest (Abstract). It should be noted the application of Douglass et al. is '*NECESSITATED BY AMENDMENT*' based on Applicants amendment to claim 1, wherein Douglass et al. provides for the scanning at a first magnification followed by acquiring and recording at a high magnification (which is considered to be any magnification higher than the first) (Column 2, lines 25-36). The biological specimen for the detection, identification, quantitation, and characterization can be cancer, blood, biological fluid, etc. (instant claims 4 and 17-19; Column 1, lines 9-17). Specimens are indicated as being generally stained with one or more industry standard stains (i.e. DAB, New Fuschin, AEC) (instant claim 1 "fluorophores"; Column 14, lines 26-33). A slide is scanned at a first magnification (i.e. low) to identify candidate cells based on their color, size, shape characteristics, and the X-Y locations of

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candidate cells are stored (instant claim 1 “scanning...at a first magnification...registering the location...acquiring and recording a first image...”; Column 6, lines 2-6). Once the scanning at the first magnification is complete images are taken at a higher magnification, wherein the image is stored (instant claim 1 “acquiring and recording a second image...at higher magnification...”; Column 6, lines 7-10). The image processing includes low pass filtering, background suppression, artifact suppression, morphological processing, and blob analysis (claim 1 “optical or electronic filter...blocking photons”; Column 13, lines 23-25). These images are compared to identify objects of interest/candidate body (claim 1 “indexing...inspecting”; Column 13, lines 49-67; Column 14, lines 1-5; and Column 18, lines 23-29). Thus, Douglass et al. anticipates the instantly claimed invention.

OBJECTION TO CLAIMS

Claim 2 is objected to for having multiple periods within the instant claim. For example, “a.” should be replaced with “a)”, “b.” should be replaced with “b)”, etc. Appropriate correction is requested.

Claim 7 recites the language “field specimen”, which appears inconsistent with the language format found in instant claims 1-6, 17-19, and 29, wherein “specimen field” is utilized. Appropriate correction is requested.

ACTION IS FINAL, AS NECESSITATED BY AMENDMENT

Applicants’ amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either 571-273-8300.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Examiner Initials: *CSM*

Date: *February 21, 2005*

Ardin H. Marschel 2/21/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER